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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,967	12/26/2001	Shigeru Kamei	087147-0443B	2213

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,967	KAMEI ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *4-10 and 17-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' election of Group I is acknowledged. Also acknowledged are the elected species:

a) the following peptide (THF = tetrahydrofuranyl):

THF-CO-Gly-D-2Na1-D-4C1Phe-D-3Pal-Ser-(NMe)Tyr-D-Lys(Nic)-Leu-Lys(Nisp)-Pro-D-Ala-NH_2

(b) a copolymer of lactic acid and glycolic acid (75/25) having a weight average molecular weight of about 10,000;

(c) the composition is in the form of microcapsules;

(d) the composition is a solid finely divided particle powder;

(e) no other material is present in the elected composition.

Claims 19-25 are withdrawn from consideration pursuant to the restriction. Claims 4, 17-18 are withdrawn because they do not encompass the elected peptide. Claims 5-10 are also withdrawn. The elected composition is such that the "biodegradable polymer" of claim 1 is a copolymer of lactic acid and glycolic acid. Nothing more is required. By contrast, claims 5-10 require that one starts with a polylactic acid (which does not contain glycolic acid), and combines that with a copolymer of lactic acid and glycolic acid. Such a mixture of a homopolymer and a copolymer is not the same as that present in the elected

composition. Claims 1-3 and 11-16 are examined in this Office action.

✧

Truncation of the abstract is required so that the text of the abstract is no longer than about 2/3 of a page.

✧

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,480,868. . Although the conflicting claims are not identical, they are not patentably distinct from each other.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application . See 37 CFR 1.78(d)

✧

The following is a quotation of the first paragraph of 35 U.S.C. '112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have asserted that the compound of claim 16 is an LH-RH antagonist. However, there is no evidence that this is the case. Certainly, other antagonists of LH-RH are known. But the reality in pharmacology is that one cannot "predict" receptor antagonism or even receptor binding merely be viewing the structure of a compound. Minor changes in structure can result in elimination of activity. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Given the unpredictability of structure/activity relationships, "undue experimenation" would be required of the skilled artisan to use the composition of claim 16 to antagonize LH-RH.

✧

Claims 1-3 and 11-16 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 1, it is recited that R_5, is an amino group which "may optionally be" substituted. This phrase ("may optionally") is somewhat redundant, i.e., "may" or

"optionally" would be sufficient.

- In claim 1, second-to-last line, the word "thereof" should be followed by a semicolon, to separate the description of the peptide from that of the polymer.

- In each of claims 2 and 3, the phrase "may optionally be" is somewhat redundant, i.e., "may" or "optionally" would be sufficient.

- Claim 12 recites the phrase "about 5000 to 25000", thus rendering the claim indefinite as to the lower limit.

- Claim 13 recites the phrase "about 1.2 to 4", thus rendering the claim indefinite as to the lower limit.

- Claim 14 recites the phrase "about 0.01% to 50%", thus rendering the claim indefinite as to the lower limit.

- Claim 16 recites "or its acetate". The claim should make clear whether "acetate" means that the serine hydroxyl group is acetylated, or whether an acetate salt of the indicated peptide is intended.

✧

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

> granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 11 are rejected under 35 U.S.C. §102(e) as being anticipated by Haviv (USP 5,110,904).

Haviv discloses (cols 12-25) various peptides falling within the scope of instant claim 1. Also disclosed (col 27, line 8+) is that the peptide can be combined with a PLA/PLG copolymer. Thus, the claims are anticipated.

✧

The following is a quotation of 35 U.S.C. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-3 and 11-15 are rejected under 35 U.S.C. §103 as being unpatentable over Haviv (USP 5,110,904) in view of Boswell (USP 3,773,919).

The teachings of Haviv are indicated above. Boswell discloses various PLA/PLG polymers for use in pharmaceutical compositions. Boswell does not disclose any of the LH-RH antagonists to which the instant claims are drawn.

An important point to be made is that there can be no argument as to the motivation to combine references. Haviv provides (col 27, line 8+) a clear "roadmap" to the Boswell patent.

Thus, the claims are rendered obvious.

✧

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Haviv (USP 5,140,009) in view of Boswell (USP 3,773,919).

Haviv discloses various peptides falling within the scope of instant claim 1. Also disclosed (col 27, line 8+) is that the peptide can be combined with a PLA/PLG copolymer. Further discussion of the PLA/PLG copolymer is provided in Boswell. Boswell does not disclose any of the LH-RH antagonists to which the instant claims are drawn.

Thus, the claim is rendered obvious.

Reference "A35" was stricken from the IDS because a translation was not provided.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1600